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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,078	09/09/2003	Gopi M. Venkatesh	451194-092	1435

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,078	VENKATESH ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *10-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/28/05, 1/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's response filed on July 15, 2005. Applicant's election **with** traverse of the restriction requirement in the reply is acknowledged. The traversal is on the ground(s) that there is no undue burden for examining both sets of claims where classifications for both inventions are identical. This is not found persuasive because a search for the composition may not lead to information regarding a process of making the composition. The requirement is still deemed proper and is therefore made FINAL. Claims 1-14 are pending. Claims 3-5, 8-9 have been amended. Claims 10-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-9, 13-14 are examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, the term "dissolution rate controlling polymer" is indefinite. Any polymer in the composition would be reasonably expected to affect the "dissolution rate." There is no clear definition in the specification as to what a

"dissolution rate controlling polymer" actually is nor is there any explanation as to why the polymers recited in claim 5 are not "dissolution rate controlling polymers."

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear whether the concentration range (5% to 35%) pertains to the pharmaceutically acceptable filler or lactose.

Claim 5 recites the limitation "said hydrophilic binder" and "a concentration of from about 1% to about 4%." There is insufficient antecedent basis for this limitation in the claim since it is dependant on claim 4, which does not recite the phrase nor is the range within the range of the parent claim.

Claim 5 recites the limitation "in the dry form." There is insufficient antecedent basis for this limitation in the claim since it is dependant on claim 4, which states that the hydrophilic binder must be an aqueous solution.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8-9, 13-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Rampal et al. (WO 03/017981).

Rampel et al. teach a controlled release formulation of clarithromycin (abstract). The composition in Example 7 is comprised of clarithromycin (84.8%), hydrophilic binder and film coat (methocel - hydroxypropylmethylcellulose) (1.75%), lactose (6.36%), magnesium stearate (1.06%), talc (0.85%), and colloidal silicon dioxide (0.43%). The composition in Example 8 is comprised of clarithromycin (84.6%), hydrophilic binder and film coat (methocel - hydroxypropylmethylcellulose) (2.35%), lactose (4.2%), water-soluble excipient (polyvinylpyrrolidone) (2.1%), magnesium stearate (1.1%), talc (0.85%), and colloidal silicon dioxide (0.40%).

Rampel et al. also teach a method of preparation in Example 7. Clarithromycin was blended with the two polymers and lactose and granulated with a solution of methocel E50 in water. The granules were dried, sized, mixed with the remaining excipients and compressed to tablets (pg. 12, lines 10-12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 7 is rejected under 35 U.S.C. 103(a) as being obvious over Rampal et al. (WO 03/017981) as applied to claims 1-6, 8-9, 13-14 in view of Vanderbist et al. (WO 02/24174 A2).

The instant claims are directed to an extended release tablet comprised of a macrolide antibiotic, water-soluble excipients, and a tableting aid (microcrystalline cellulose).

Rampal et al. teach as discussed above, however fails to disclose a composition comprising microcrystalline cellulose in the amount of not more than 5% by weight.

Vanderbist et al. teach a sustained release composition containing clarithromycin (abstract) with between 5 to 50% by weight of microcrystalline cellulose (pg. 13, lines 6-8).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, for Rampal et al. to add 5% of microcrystalline cellulose to the composition as disclosed by Vanderbist et al.

A person of ordinary skill in the art would have been motivated to add microcrystalline cellulose to the composition taught by Rampel et al. because according

to Vanderbist et al., excipients such as microcrystalline cellulose always guarantees the optimal dissolution of clarithromycin (pg. 7, lines 24-28).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SHENGJUN WANG
PRIMARY EXAMINER